



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,404	03/31/2004	Samuel Achilefu	MRD / 54DV	5388
<div>7590      05/25/2007</div> <div>David E. Jefferies Wood, Herron &amp; Evans, L.L.P. 2700 Carew Tower 441 Vine Street Cincinnati, OH 45202-2917</div> <div>EXAMINER PERREIRA, MELISSA JEAN</div> <div>ART UNIT      PAPER NUMBER</div> <div>1618</div> <div>MAIL DATE      DELIVERY MODE</div> <div>05/25/2007      PAPER</div>				

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,404	<b>Applicant(s)</b> ACHILEFU ET AL.	
	<b>Examiner</b> Melissa Perreira	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4-14,16,17,19 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 4-14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,17,19 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/8/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/10/07 has been entered.

2. Claims 1,4-14,16,17,19 and 23 are pending in the application. Claims 4-14 and 16 are withdrawn from consideration.

### ***Claim Objections***

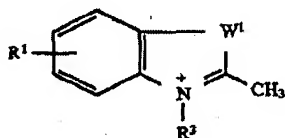
3. Claim 1 is objected to because of the following informalities: the instant claims recites, "Y<sub>1</sub> is **independently** selected from the group consisting of". This is not correctly stated as there is no other variable to choose from. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

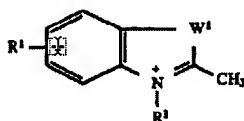
4. Claims 1,17,19 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Fung et al. (US 5,672,332).

5. Fung et al. (US 5,672,332) teaches of the compounds below where  $R^1$  is H,  $C_{1-10}$  hydroxyalkyl,  $C_{1-10}$  aryl,  $C_{1-10}$  alkoxy, halogen, nitro;  $R^3$  is  $C_{1-10}$  aryl,  $C_{1-10}$  alkoxyalkyl;  $W^1$  is  $CR^9R^{10}$  where  $R^9$  and  $R^{10}$  may be  $C_{1-10}$  alkoxyalkyl,  $-(CH_2)_m-N(R^6)(R^7)/$ aminoalkyl (column 2, lines 31-67; abstract; column 3, lines 30-34).



6. Claims 1,17,19 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Rajagopalan et al. (US 5,672,333).

7. Rajagopalan et al. (US 5,672,333) teaches of the compounds below where  $R^1$  is H,  $C_{1-10}$  hydroxyalkyl,  $C_{1-10}$  aryl,  $C_{1-10}$  alkoxy, halogen, nitro;  $R^3$  is  $C_{1-10}$  aryl,  $C_{1-10}$  alkoxyalkyl;  $W^1$  is  $CR^9R^{10}$  where  $R^9$  and  $R^{10}$  may be  $C_{1-10}$  alkoxyalkyl,  $-(CH_2)_m-N(R^6)(R^7)/$ aminoalkyl (column 2, lines 28-62; column 3, lines 20-25).

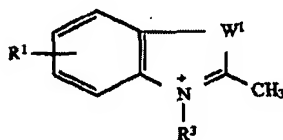


8. Claims 1,17,19 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Rajagopal et al. (US 5,709,845).

9. Rajagopal et al. (US 5,709,845) teaches of the compounds below where  $R^1$  is H,  $C_{1-10}$  hydroxyalkyl,  $C_{1-10}$  aryl,  $C_{1-10}$  alkoxy, halogen, nitro;  $R^3$  is  $C_{1-10}$  aryl,  $C_{1-10}$

Art Unit: 1618

alkoxyalkyl;  $W^1$  is  $CR^9R^{10}$  where  $R^9$  and  $R^{10}$  may be  $C_{1-10}$  alkoxyalkyl,  $-(CH_2)_m-$   
 $N(R^6)(R^7)$ /aminoalkyl (column 2, lines 56-67; abstract; column 3, lines 1-12 and 40-45).



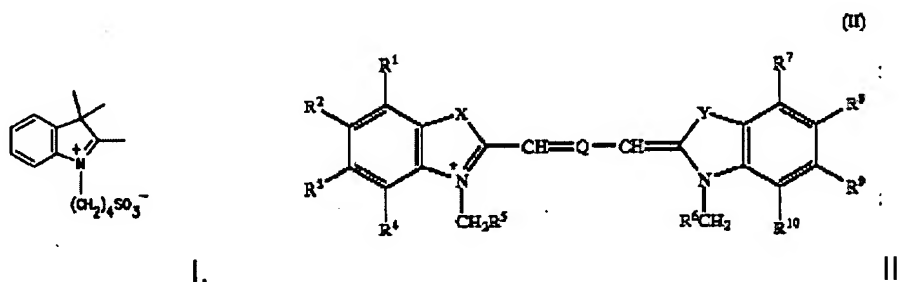
### Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1,17,19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Licha et al. (WO98/47538 as translated in US 6,534,041B1).

12. Licha et al. (WO98/47538 as translated in US 6,534,041B1) teaches of the compounds of formula II (below) which are prepared via intermediates, such as that of formula I (2,3,3-trimethyl-4,5-benzo-3H-indolene) (below) (Figure 1; column 11, lines 20-30).



Art Unit: 1618

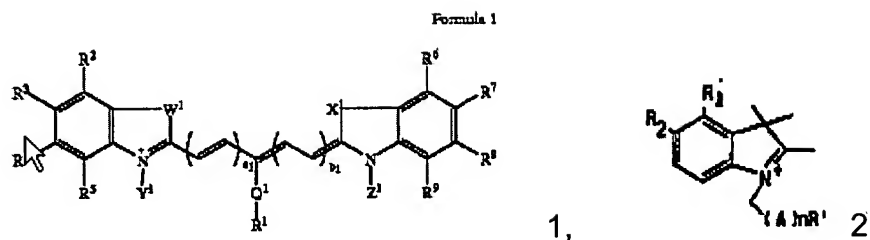
13.  $R^5$  of the composition of formula II may be a  $C_{1-50}$  alkyl chain interrupted by 0 to 15 oxygen atoms and/or 0 to 3 carbonyl groups and/or is substituted with 0 to 5 hydroxy groups, etc. (column 3, lines 25-30 and 44-50; column 11, lines 36-53), i.e.

polyalkoxyalkyl, aminoalkyl, etc. X may be  $>C(CH_2R^{13})(CH_2R^{14})$  where  $R^{13}$  and  $R^{14}$  may be  $C_{1-50}$  alkyl chain interrupted by 0 to 15 oxygen atoms and/or is substituted with 0 to 5 hydroxy groups, etc (column 4, lines 21-33). It would have been obvious at the time of the invention that the intermediate of formula I (2,3,3-trimethyl-4,5-benzo-3H-indolene) necessarily contains the same  $R^5$  substituent, i.e. aminoalkyl, polyalkoxyalkyl in place of the  $C_{1-4}$  sulfoalkyl chain (formula I) and X substituent in order to generate the composition of formula II as the final product. The resulting polyalkoxyalkyl, aminoalkyl, etc. substituted 2,3,3-trimethyl-4,5-benzo-3H-indolene intermediates of Licha et al. encompass the compositions of the instant claims, i.e. C1-C20 polyalkoxyalkyl substituted.

14. Claims 1,17,19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Achilefu et al. (US 6,180,085B1).

15. Achilefu et al. (US 6,180,085B1) discloses compositions of formula 1 (below) which are prepared via intermediates, such as that of formula 2 where  $R_1$  and  $R_2$  may be hydrogen (2,3,3-trimethyl-4,5-benzo-3H-indolene) (below) (fig 1, sheet 1; column 2, lines 45-54):

Art Unit: 1618



16.  $Y^1$  of the composition of formula 1 may be  $-(CH_2)_i-N(R^{15})-CH_2-(CH_2-O-CH_2)_j-CH_2-CO_2H$  or  $-(CH_2)_e-NH_2$  (aminoalkyl), etc. (column 2, lines 62 and 64-65) which encompass those substituents of the instant claims.  $W^1$  may be  $CR^{10}R^{11}$  where  $R^{10}$  and  $R^{11}$  may be C1-C10 alkoxy, polyalkoxyalkyl,  $-(CH_2)_f-NH_2$ /alkylamine, etc. (column 2, lines 55,57 and 67; column 3, lines 1-4). It would have been obvious at the time of the invention that the intermediate of formula 2 (2,3,3-trimethyl-4,5-benzo-3H-indolene) must be substituted with the same  $W^1$  and  $Y^1$ , such as  $-(CH_2)_i-N(R^{15})-CH_2-(CH_2-O-CH_2)_j-CH_2-CO_2H$  or  $-(CH_2)_e-NH_2$ , etc. in place of the  $(A)_nR$  group (formula 2) in order to generate the final compositions of formula 1. The  $-(CH_2)_i-N(R^{15})-CH_2-(CH_2-O-CH_2)_j-CH_2-CO_2H$  or  $-(CH_2)_e-NH_2$  (aminoalkyl), etc. substituted 2,3,3-trimethyl-4,5-benzo-3H-indolene intermediates of Achilefu et al. (US 6,180,085B1) encompass the compositions of the instant claims.

### Conclusion

No claims are allowed at this time.

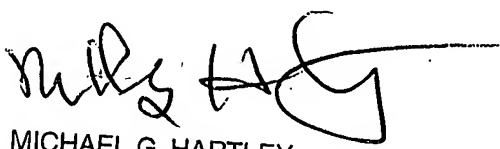
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP  
May 18, 2007

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER